INTERSPINOUS PROCESS AND SACRUM IMPLANT AND METHOD

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CLAIM OF PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 60/422,020, filed on October 29, 2002, entitled "INTERSPINOUS PROCESS AND SACRUM IMPLANT AND METHOD" (Attorney Docket No. KLYC-01075US0), which is incorporated herein by reference.

CROSS REFERENCE TO RELATED APPLICATIONS

[0002] This application is related to U.S. Provisional Application No. 60/421,915, filed October 29, 2002, entitled "INTERSPINOUS PROCESS IMPLANT WITH RADIOLUCENT SPACER AND LEAD-IN TISSUE EXPANDER" (Attorney Docket No. KLYC-01077US0), which are incorporated herein by reference. This application is also related to U.S. Patent Application No. 10/230,505, filed August 29, 2002, entitled "DEFLECTABLE SPACER FOR USE AS AN INTERSPINOUS PROCESS IMPLANT AND METHOD" (KLYC-1056USB), which is incorporated herein by reference.

FIELD OF THE INVENTION

[0003] This invention relates to an implant that is adapted to be placed between the L5 and the S1 vertebrae and method.

BACKGROUND OF THE INVENTION

[0004] As the present society ages, it is anticipated that there will be an increase in degenerative and dysfunctional spinal conditions including degenerative disk and joint diseases, spinal fractions and other problems. Pain associated with such conditions can be relieved by medication and/or surgery. The lumbosacral junction itself is exposed to significant axial, translational and rotational loads that can exacerbate the pain experienced from these degenerative conditions. Effectively managing lumbosacral region instability and pain can require that sagittal balance and neurological function be maintained. This is traditionally done by internal fixation and/or bone fusion.

[0005] Over the years, a variety of implants have been developed in order to relieve the pain associated with such degenerative and dysfunctional conditions. For example, U.S. Patents 5,127,912, 5,300,073 and 6,197,028 to Ray et al. are related patents that disclose a sacral implant system.

[0006] U.S. Patent 4,773,402 to Asher et al. is directed to a dorsal trans-sacral surgical implant.

[0007] U.S. Patent 4,047,523 to Hall discloses a surgical sacral anchor implant that is a surgical implant for securing a cable to the sacrum to correct the curvature of the spine.

[0008] None of these solutions provide an implant that is minimally invasive while restoring stability to the region without interfering with natural movement. Nor are the implants easily adjustable after the surgery has been completed. Accordingly, what is needed is an implant for restoring stability to the lower back.

SUMMARY OF THE INVENTION

[0009] Embodiments of the present invention are directed to providing a minimally invasive implant for alleviating discomfort and lack of stability in the lumbosacral region of the spine. The implant includes a base for attaching to the medial sacral lamina. A spacer is provided that engages the base and is positioned to abut the spinous process of the L5 vertebrae.

[0010] Other aspects, objects, features, and elements of the embodiments of the invention are described or are evident from the accompanying specification, claims and figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] **FIG. 1** is a side perspective view of an embodiment of the assembled implant of the invention.

[0012] **FIG. 2A** is a perspective side view of an embodiment of the base of the implant of the invention. **FIG. 2B** is a cross-sectional plan view of an embodiment of the base of the implant of the invention. **FIG. 2C** is a left side view of the embodiment of Figure **FIG. 2A**.

[0013] **FIG. 3A** is a perspective view of an embodiment of the beam and spacer of the implant of the invention. **FIG. 3B** is side view of an embodiment of the beam and spacer of the implant of the invention. **FIG. 3C** is a plan view of an embodiment of the beam and spacer of the implant of the invention. **FIGS. 3D** through **3G** are plan views of alternative embodiments of the beam and spacer of the implant of the invention shown in **FIG. 3A**.

[0014] **FIG. 4A** is a posterior view of an embodiment of the assembled implant of the invention. **FIG. 4B** is an anterior view of an embodiment of the assembled implant of the invention. **FIG. 4C** is a side view of an embodiment

of the assembled implant of the invention. **FIG. 4D** is a top view of an embodiment of the assembled implant of the invention.

[0015] **FIG. 5A** is a side view of an embodiment of the implant of the invention implanted between the S1 and L5 vertebrae in the spine. **FIG. 5B** is a posterior view of an embodiment of the implant of the invention implanted between the S1 and L5 vertebrae in the spine.

[0016] **FIG. 6** is a block diagram of an embodiment of the method of implanting the implant between the S1 and L5 vertebrae.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

[0017] The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of the invention disclosed, the specification and drawings of all patents, patent publications, and patent applications cited in this application are incorporated herein by reference.

[0018] Turning now to **FIG. 1**, a side perspective view of an embodiment of the assembled implant ***100*** of the invention. A base ***110*** is provided that engages the median sacral lamina upon implantation. A beam ***140*** and spacer ***142*** are attached to the base ***110*** and a nut ***160*** or other suitable device holds the beam ***140*** to the base ***110***. The beam ***140*** can be adjusted vertically to enable the spacer ***142*** to engage the spinous process of the L5 vertebra to achieve a desired amount of spacing between the L5 and

S1 vertebra and to spread the mechanical load from the L5 spinous process across the implant. As desired, implant ***100*** can be made of titanium which is radiopague. Other suitable material includes by way of example only polyetheretherketone (PEEK), polyetherketoneketone (PEKK), polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), all of which are radiolucent.

[0019] The base ***110*** is shown in a perspective view in **FIG. 2A**. The base ***110*** has a body ***220*** with a threaded post ***222*** extending from a central platform ***224*** thereof. The central platform can be raised as shown to enable the base ***110*** to engage the median sacral lamina without interfering with the anatomy thereof. The post ***222*** is of a length to fit within the elongated aperture of the beam ***140*** and engage a nut ***160*** on the other side thereof. The nut ***160*** can be tightened to hold the beam in place. As will be appreciated by those of skill in the art, where another mechanism is employed to secure the beam ***140*** onto the post ***222***, threading may not be required. Alternatively, a hexagonal recess ***222*** (**FIG. 2B**) can be provided to enable the nut ***160*** to be tightened by an Allen wrench. Alternatively, the nut ***160*** can have a hexagonal outer shape to facilitate tightening thereof.

[0020] The central platform ***224*** of the body ***220*** extends to a first portion or flange ***230*** and a second portion or flange ***231***, on either side of the platform ***224***. Each of the portions ***230, 231*** can also be provided with one or more apertures ***234*** for engaging, for example, screws ***239*** to further secure the base ***110*** to the sacrum (shown in more detail with respect to **FIG. 5B** described below). The portions ***230, 231*** are configured such that one surface ***232, 233*** (**FIG. 2B**) of each portion abuts the sacrum. At least one of the portions ***230, 231*** extends into a hook ***236*** for engaging the median sacral lamina. Preferably, each of the portions ***230, 231*** extends into a corresponding hook ***236, 237*** for engaging a first and second portion of the medial sacral lamina. **FIG. 2B** shows a posterior view of an embodiment of the

base ***110*** of the implant of the invention. As evidenced from this view, the flanges ***230, 231*** are angled away from each other to facilitate the hooks ***236, 237*** engaging the median sacral lamina. The gap ***250*** between the flanges ***230, 231*** enable the base ***110*** to engage the sacrum. **FIG. 2C** shows a side view of the base ***110*** with the side ***231*** of the base ***110***, the hook ***237***, the platform ***224*** and the threaded post ***222***.

[0021] **FIG. 3A** is a perspective view of the beam ***140*** where the spacer ***142***, at one end thereof, is depicted. The beam ***140*** has an elongated aperture ***342*** along a portion of its length. The elongated aperture ***342*** has a width sufficient to enable the post ***222*** of the base ***110*** to pass therethrough, but not so wide that when the fixation mechanism, such as the nut ***160***, is attached to the post ***222***, that the fixation mechanism would not secure the beam ***140*** to the base ***110*** at a desired location of the beam ***140*** relative to the base ***110***. Rather, the width is such that the post ***222*** passes through the aperture ***342,*** and is engaged by the nut ***160***, or other fixation mechanism, to hold the beam ***140*** to the base ***110***.

[0022] The spacer ***142*** is shaped so that it has a bulbous profile, as shown in **FIG. 3A**. In this embodiment, the spacer ***142*** is elliptically shaped. However, the spacer ***142*** can also be oval, ovoid, egg, cylindrical and race-track (**FIG. 3F**) in shape. The spacer can also be hollow (**FIG. 3F**) to make the spacer more flexible and deflectable. Further, the spacer can be made in multiple pieces with an outer spacer spaced ***350*** from an inner spacer ***352*** (**FIG. 3G**) to allow for deflection of the spacer due to backward bending of the patient. This beam ***140*** includes the previously described elongated slot ***342*** which allows the spacer ***140*** to be positioned in a variety of positions relative to the base ***110*** in order for the implant ***100*** to adjust to the structure and shape of the spine of the patient. Additionally, the aperture ***342*** can be replaced by a plurality of apertures along its length as shown in **FIG. 3D**, any one of which can be sized to accept the post ***222*** of the base ***110***.

Alternatively, the aperture ***342*** can have an interior surface that is scalloped ***348***, as shown in **FIG. 3E**. In such a configuration, each scallop ***348*** is dimensioned to accept the post ***222***. All these embodiments assist in the placement of the beam ***140*** relative to the base ***110***.

[0023] **FIG. 4A** shows a posterior view of an embodiment of the implant ***100*** in its assembled condition, while **FIG. 4B** shows an anterior view of the implant ***100*** in its assembled condition. As evidenced by the figures, the beam ***140*** can be positioned relative to the base ***110*** so that the spacer ***142*** sits substantially above the base ***110***, as shown in **FIG. 4A**, or so that the spacer ***142*** sits flush with the tops of the flanges ***230, 231***.

[0024] **FIG. 4C** shows a side view of an embodiment of the implant ***100*** assembled. As evidenced by **FIG. 4C**, the hooks ***236, 237*** are configured to provide a space ***460*** between the flange ***230, 231*** and the hook ***236, 237*** into which the median sacral lamina fits.

[0025] **FIG. 4D** shows a top view of the assembled implant ***100*** of an embodiment of the invention with the upper surface of the flanges ***236, 237***, the upper surface of the central platform ***224*** of the body, and the nut ***160*** engaging the post ***222*** of the base ***110***.

[0026] As will be appreciated by those of skill in the art, the implant ***100*** of the invention can be manufactured from a variety of biocompatible materials including titanium, suitable medical grade alloys such as nitinol, or thermoplastics using a variety of techniques such as extrusion, injection, and compression molding and/or machining techniques. Additionally, the implant ***100*** can have a structural frame that is comprised of a second material. For example, a structural frame of titanium can be provided which is surrounded by an appropriate thermoplastic to achieve the desired final shape of the implant in accordance with the teachings of the invention.

[0027] For example, at least part of the implant can be comprised of a polymer. The polymer can be, for example, a polyketone such as

polyetheretherketone (PEEK), as previously indicated. Still, more specifically, the material can be PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com). The implant ***100*** can be formed by extrusion, injection, compression molding and/or machining techniques with such material. This material has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load. Further, in this embodiment the PEEK has the following approximate properties:

Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 Gpa

[0028] It should be noted that the material selected could also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0029] As will be appreciated by those of skill in the art, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate

materials that resist fatigue, have good memory, are flexible, and/or deflectable have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. The spacer can also be comprised of polyetherketoneketone (PEKK).

[0030] Other materials that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetherether-ketoneketone (PEEKK), and, generally, a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics. The spacer can also be made of titanium.

[0031] Reference to appropriate polymers that can be used in the spacer can be made to the following documents. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials."

[0032] Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California (www.polymertech.com), may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used as well without departing from the scope of the invention.

[0033] **FIG. 5A** shows a side view of an embodiment of the implant ***100*** of the invention implanted between the S1 and the L5 vertebrae. As evidenced in this figure, the spacer ***142*** is positioned so that it abuts the spinous process of the L5 vertebrae. The width of the spacer ***142*** is such that it enables the spacer ***142*** to engage the spinous process of the L5 vertebrae

while enabling the mechanical load of the L5 vertebrae to be spread out over the spacer ***142***.

[0034] **FIG. 5B** illustrates a posterior view of an embodiment of the implant ***100*** of the invention implanted between the S1 and the L5 vertebrae. This perspective also shows the spacer ***142*** positioned to abut the spinous process of the L5 vertebrae. However, as is more readily apparent from this view, the positioning of the spacer ***142*** relative to the spinous process is facilitated by adjusting the position of the spacer ***142*** by moving the beam ***140*** relative to the post ***222*** in a first or second direction along the elongated aperture ***342***. Additionally, as will be apparent to those of skill in the art, the positioning of the spacer ***142*** relative to the spinous process can also be adjusted at a later time (*e.g.,* after implant).

[0035] **FIG. 6** shows a block diagram of the steps of the method of implanting an implant of this invention. The first step involves exposing the lumbosacral area ***610***. After exposing the region, the base ***110*** of the implant ***100*** is implanted such that it engages the median sacral lamina ***620***. At this point, if desired, the base ***110*** can be adhered to the median sacral lamina ***630*** by screwing the base ***110*** to the lamina by installing screws through the apertures ***234*** provided in the flanges ***230, 231*** of the base ***110***. Alternatively, the base ***110*** can be snug fit to the lamina.

[0036] If not preassembled, at this point the beam ***140*** is placed on the base ***110*** by engaging the beam ***140*** with the post ***222*** via the aperture ***342*** of the beam ***140*** (step ***640***). The beam ***140*** can be moved in a first and/or second direction to place the spacer ***142*** in an optimum position with respect to the spinous process of the L5 vertebrae ***650***. Once the beam ***140*** spacer ***142*** assembly is positioned, the nut ***160,*** or other adhering mechanism, is tightened to the post ***222*** to keep the beam ***140*** spacer ***142*** in position relative to the spinous process of the L5 vertebrae (step ***660***). If desired, a plurality of beams of different lengths or having differently shaped distal ends can be

provided in a kit. During a surgical procedure, the doctor can select the beam with the length and the distal end shape that is appropriate for the anatomy of the patient. Thereafter, the wound is closed ***670***. Generally, the implant has been designed to be implanted without altering the L5 or S1 bone. The offset platform ***224*** and the slot ***250*** have been designed to accommodate the S1 form. However, due the configuration of the S1 bone, a small bone piece such as from the median sacral crest may need to be removed in order to accommodate the platform ***224***. The removal of this bone should not effect the stability of the bone structure as there is no bearing load from the implant ***100*** or the spine placed on the location where the bone is removed.

[0037] If at a later time it is determined that the location of the spacer ***142*** relative to the L5 spinous process needs to be changed, the nut ***160*** can be surgically removed (through, for example, a cannula) and the beam ***140*** and spacer ***142*** moved toward or away from the spinous process, as desired.

[0038] The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and its equivalence.